

General

Guideline Title

ACR Appropriateness Criteria® clinically suspected adnexal mass.

Bibliographic Source(s)

Harris RD, Javitt MC, Glanc P, Brown DL, Dubinsky T, Harisinghani MG, Khati NJ, Kim YB, Mitchell DG, Pandharipande PV, Pannu HK, Podrasky AE, Royal HD, Shipp TD, Siegel CL, Simpson L, Wall DJ, Wong-You-Cheong JJ, Zelop CM, Expert Panel on Women's Imaging. ACR Appropriateness Criteria® clinically suspected adnexal mass. [online publication]. Reston (VA): American College of Radiology (ACR); 2012. 13 p. [44 references]

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Lev-Toaff AS, Horrow MM, Andreotti RF, Lee SI, DeJesus Allison SO, Bennett GL, Brown DL, Glanc P, Horowitz NS, Javitt MC, Podrasky AE, Scoutt LM, Zelop CM, Expert Panel on Women's Imaging. ACR Appropriateness Criteria® clinically suspected adnexal mass. [online publication]. Reston (VA): American College of Radiology (ACR); 2009. 9 p.

Recommendations

Major Recommendations

ACR Appropriateness Criteria®

Clinical Condition: Clinically Suspected Adnexal Mass

Variant 1: Reproductive age female (not pregnant). Initial evaluation.

Radiologic Procedure	Rating	Comments	RRL*
US pelvis transvaginal	9	All three tests (TVS, TAS, and Doppler) may be performed depending on the clinical circumstances.	О
US pelvis with Doppler	9	All three tests (TVS, TAS, and Doppler) may be performed depending on the clinical circumstances. Color or power US is recommended, less so spectral Doppler.	O
Rating Scale: 1.2.3 Usually not appropriate	e: 4.5.6 Mav be annronriate:	7.8.9 Usually appropriate	*Relative

US pelvis transabdominal Radiologic Procedure	Rating	All three tests (TVS, TAS, and Doppler) may be performed depending on the clinical circumstances.	RRL*
MRI pelvis without and without contrast	6	See statement regarding contrast in text under "Anticipated Exceptions."	О
MRI pelvis without contrast	5		О
CT pelvis without contrast	2		
CT pelvis with contrast	2		
CT pelvis without and with contrast	2		
Image-guided aspiration or biopsy adnexal mass	2		Varies
FDG-PET/CT whole body	1		
Rating Scale: 1,2,3 Usually not appropriate	te; 4,5,6 May be appropriate;	7,8,9 Usually appropriate	*Relative Radiation Level

<u>Variant 2</u>: Reproductive age female (not pregnant) with complex or solid mass detected by pelvic sonography. Follow-up recommendations.

Radiologic Procedure	Rating	Comments	RRL*
US pelvis transvaginal	9	All three tests (TVS, TAS, and Doppler) may be performed depending on the clinical circumstances.	О
US pelvis with Doppler	9	All three tests (TVS, TAS, and Doppler) may be performed depending on the clinical circumstances. Color or power US is recommended, less so spectral Doppler.	0
US pelvis transabdominal	8	All three tests (TVS, TAS, and Doppler) may be performed depending on the clinical circumstances.	О
MRI pelvis without and with contrast	5	See statement regarding contrast in text under "Anticipated Exceptions."	О
MRI pelvis without contrast	4		О
CT pelvis with contrast	3		
Rating Scale Hold Columns y not appropria	ate; <u>24</u> ,5,6 May be appropriate;	7,8,9 Usually appropriate	*Relativ

Radiologic Procedure	Rating	Comments	RRL*
CT pelvis without and with contrast	2		
FDG-PET/CT whole body	2		
Image-guided aspiration or biopsy adnexal mass	2		Varies
Rating Scale: 1,2,3 Usually not appropriate	te; 4,5,6 May be appropriate;	7,8,9 Usually appropriate	*Relative Radiation Level

<u>Variant 3</u>: Reproductive age female (not pregnant) with complex or solid mass detected by pelvic sonography getting smaller at short-term follow-up. (If resolved, no further imaging necessary.)

Radiologic Procedure	Rating	Comments	RRL*
US pelvis transvaginal	9	Either TAS and/or TVS may be tailored as appropriate to visualize the lesion.	О
US pelvis with Doppler	9	With either TAS or TVS to exclude vascular flow. Color or power US is recommended, less so spectral Doppler.	O
US pelvis transabdominal	8	Either TAS and/or TVS may be tailored as appropriate to visualize the lesion.	О
MRI pelvis without contrast	3		О
MRI pelvis without and with contrast	3	May be useful for endometriosis and associated scarring.	О
CT pelvis without contrast	1		
CT pelvis with contrast	1		
CT pelvis without and with contrast	1		
FDG-PET/CT whole body	1		
Rating Scale: 1.2.3 Usually not appropri	ate: 456 May be an	propriete: 7 8 0 I sually appropriete	*Relativ

Image guided aspiration or biopsy Radiologic Procedure adnexal mass	Rating	Comments	KREes
Rating Scale: 1,2,3 Usually not appropriat	e; 4,5,6 May be appropriate;	7,8,9 Usually appropriate	*Relative Radiation Level

<u>Variant 4</u>: Reproductive age female (not pregnant) with indeterminate complex or solid mass that is persistent or enlarging on pelvic sonography at short-term follow-up. (In the appropriate clinical setting, surgery may be performed in lieu of additional imaging.)

Radiologic Procedure	Rating	Comments	RRL*
MRI pelvis without and with contrast	8	See statement regarding contrast in text under "Anticipated Exceptions."	0
MRI pelvis without contrast	6	If patient is unable to tolerate contrast.	О
US pelvis transvaginal	5		О
US pelvis transabdominal	5		О
US pelvis with Doppler	5		О
CT pelvis with contrast	4	If patient cannot get MRI.	
CT pelvis without contrast	2		
CT pelvis without and with contrast	2		
FDG-PET/CT whole body	2	Not appropriate for tissue characterization of adnexal	
	_	lesions. For ovarian cancer staging, see the NGC	
		summary ACR Appropriateness Criteria® staging and	
		follow-up of ovarian cancer.	
Rating Scale: 1,2,3 Usually not appropri	riate; 4,5,6 May be app	propriate; 7,8,9 Usually appropriate	*Relative
			Radiation
			Level

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

<u>Variant 5</u>: Reproductive age female (not pregnant). Initial sonography demonstrates a large and apparently simple cyst >5 cm in diameter.

Radiologic Procedure	Rating	Comments	RRL*
US pelvis transvaginal	9	Either TAS and/or TVS may be tailored as appropriate to visualize the lesion. If it is >5 cm, but ≤7 cm annual follow-up is recommended.	О
US pelvis with Doppler	9	With either TAS or TVS to exclude vascular flow.	О
Reating Isis at embabaddisinally not appropriate	e;8,5,6 May be appropriate;	7 PstpletUsuallyanot/onopiPlats may be tailored as	CRelative

Radiologic Procedure	Rating	appropriate to visualize the lesion. If it is >5 cm, but <pre><7 cm annual follow-up is recommended.</pre>	RRL*
MRI pelvis without and with contrast	4	MRI may be useful if the cyst is indeterminate on US or inadequately evaluated due to technical limitations. See statement regarding contrast in text under "Anticipated Exceptions."	O
MRI pelvis without contrast	3		О
CT pelvis with contrast	2		
Image-guided aspiration or biopsy adnexal mass	2	Not appropriate for diagnosis, unless infectious etiology is suspected. May be used as a therapeutic tool.	Varies
CT pelvis without contrast	1		
CT pelvis without and with contrast	1		
FDG-PET/CT whole body	1		
Rating Scale: 1,2,3 Usually not appropri	iate; 4,5,6 May be appropriate	e; 7,8,9 Usually appropriate	*Relative Radiation Level

<u>Variant 6</u>: Postmenopausal female (>12 months amenorrhea). Initial evaluation.

Radiologic Procedure	Rating	Comments	RRL*
US pelvis transvaginal	9	All three tests (TVS, TAS, and Doppler) may be performed depending on the clinical circumstances.	О
US pelvis with Doppler	9	All three tests (TVS, TAS, and Doppler) may be performed depending on the clinical circumstances. Color or power US is recommended, less so spectral Doppler.	О
US pelvis transabdominal	8	All three tests (TVS, TAS, and Doppler) may be performed depending on the clinical circumstances.	О
MRI pelvis without and with contrast	5	See statement regarding contrast in text under "Anticipated Exceptions."	О
MRI pelvis without contrast	4		О
Rating Scale it locate blaundy not appropria	ate; 4,5,6 May be appropriate;	7,8,9 Usually appropriate	*Relative Radiation

Radiologic Procedure	Rating	Comments	RRL*
CT pelvis with contrast	2		
FDG-PET/CT whole body	2		
CT pelvis without and with contrast	1		
Image-guided aspiration or biopsy adnexal mass	1		Varies
Rating Scale: 1,2,3 Usually not appropria	te; 4,5,6 May be appropriate;	7,8,9 Usually appropriate	*Relative Radiation Level

<u>Variant 7</u>: Postmenopausal female (>12 months amenorrhea) with a simple ovarian cyst >1 cm in diameter by pelvic sonography. Follow-up recommendations. (See narrative for information regarding CA-125.)

9	All three tests (TVS, TAS, and Doppler) may be performed depending on the clinical circumstances. Use of annual follow-up to ensure cyst is stable, but if it is >7 cm consider MRI.	О
9	All three tests (TVC TAC and Daniel)	
	All three tests (TVS, TAS, and Doppler) may be performed depending on the clinical circumstances.	О
8	All three tests (TVS, TAS, and Doppler) may be performed depending on the clinical circumstances. Use of annual follow-up to ensure cyst is stable, but if it is >7 cm consider MRI.	О
3	Generally only considered for simple cysts >7 cm.	О
2		О
2		
2		
ate; <u>4</u> ,5,6 May be appropriate;	7,8,9 Usually appropriate	*Relative Radiation Level
	2	performed depending on the clinical circumstances. Use of annual follow-up to ensure cyst is stable, but if it is >7 cm consider MRI. Generally only considered for simple cysts >7 cm.

Radiologic Procedure CT pelvis without and with contrast	Rating 1	Comments	RRL*
1			
Image-guided aspiration or biopsy adnexal mass	1		Varies
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate		*Relative Radiation Level	

<u>Variant 8</u>: Postmenopausal female (>12 months amenorrhea) with a complex or solid adnexal mass seen by pelvic sonography. Follow-up recommendations. (See narrative for information regarding CA-125.) (In the appropriate clinical setting, surgery may be performed in lieu of additional imaging.)

Radiologic Procedure	Rating	Comments	RRL*
US pelvis transvaginal	9	All three tests (TVS, TAS, and Doppler) may be performed depending on the clinical circumstances.	
US pelvis transabdominal	9	All three tests (TVS, TAS, and Doppler) may be performed depending on the clinical circumstances.	
US pelvis with Doppler	9	All three tests (TVS, TAS, and Doppler) may be performed depending on the clinical circumstances. Color or power US is recommended, less so spectral Doppler.	0
MRI pelvis without and with contrast	6	See statement regarding contrast in text under "Anticipated Exceptions."	
MRI pelvis without contrast	5		О
CT pelvis without and with contrast	3		
FDG-PET/CT whole body	3	May be useful in patients with known primary malignancy outside the ovary.	
CT pelvis with contrast	2		
CT pelvis without contrast	1		
Image-guided aspiration or biopsy adnexal mass	1		Varies
Rating Scale: 1,2,3 Usually not appropri	ate: 4 5 6 May be appropriat	e: 7 8 9 I Isually appropriate	*Relative

Radiologic Procedure	Rating	Comments	Radiation
			Level

Summary of Literature Review

Introduction/Background

Adnexal masses are a common problem clinically, and pelvic sonography (US), specifically endovaginal US, is the first-line imaging modality for assessing them. Its findings, however, should be correlated with the history and laboratory tests. Morphological analysis of adnexal masses with US can help narrow the differential diagnosis. Recent studies have shown that US (transvaginal plus color Doppler) may discriminate benign from malignant lesions with a sensitivity of 99.1% and a specificity of 85.9%. However, US is not always reliable for triage of patients to surgery.

Transabdominal sonography (TAS) and transvaginal sonography (TVS) are complementary. In some facilities, patients are scanned by both techniques, but most recent literature regarding adnexal mass US refers to TVS.

Transvaginal Ultrasound

The applications of TVS in evaluating adnexal masses have been well described. Because of the improved resolution of TVS, it should be used whenever possible. When an adnexal mass is large or beyond the field of view of TVS, TAS is recommended. TAS will often provide an overview of the relationship of the mass to other pelvic structures.

The improved resolution of high-frequency endoluminal transducers along with the judicious use of color Doppler interrogation increases the sensitivity for identifying malignant adnexal masses to 92% to 99%. TVS can be used not only to differentiate between cystic and solid masses but also to improve characterization and detect vascularity of the wall or internal septations, similar features of mural nodules, and the echogenicity of cystic and complex ovarian masses. The specificity of TVS for diagnosing ovarian cancer has been reported as high as 92% to 97%. TVS can help determine the origin of an adnexal mass. When evaluating a pelvic mass, it is important to determine its origin as ovarian or extraovarian. Masses arising from the ovary can be separated from extraovarian masses by identifying a rim of compressed ovarian parenchyma around the mass. Masses arising from the fallopian tube are usually seen as distended, tubular structures that arise from the superolateral aspect of the uterus. Masses arising from the uterus are usually solid and connected to the uterus by a vascular pedicle. Using TVS, attachment of a mass to the ovary or to the uterus can often be determined, using the sliding organ sign (real-time motion of a mass against adjacent organs during extrinsic pressure while using the transvaginal probe).

TVS can help in characterizing a mass sonographically as cystic, solid, or complex. Cystic masses are usually ovarian or tubal. A simple cyst is associated with five features: 1) round shape, 2) thin or imperceptible wall, 3) increased acoustic enhancement, 4) anechoic fluid, and 5) no septations or nodules.

In addition, TVS or TAS with color, power, and spectral Doppler can be used to assess the vascularity of a mass and provide a guide for aspiration of certain masses suspected to be infectious in origin. Aspiration is generally not performed for determining neoplastic cytologic origin due to the concern for spreading malignant cells into the peritoneum.

Simple Cyst

Characterization of an adnexal mass as a cyst is important for management. US identification of a simple cyst establishes a benign process in 100% of premenopausal women and in 95% to 99% of postmenopausal women. A recent consensus conference at the Society of Radiologists in Ultrasound in 2009 reviewed the management of asymptomatic ovarian and other adnexal cysts. Most cysts in premenopausal women are functional in nature and will resolve spontaneously. Most nonfunctional cysts in premenopausal women with classically complex, but benign, US features (such as endometriomas, simple cysts, teratomas, and hydrosalpinges) measuring <5 cm in diameter have been shown to remain unchanged during long-term follow-up. Therefore, it is possible to manage these lesions safely by US follow-up rather than surgical intervention in asymptomatic women.

In postmenopausal women, simple cysts are seen with a frequency of 17% to 24% and are not related to hormonal therapy or time since onset of menopause, although some have observed decreasing frequency with time after the onset of menopause. These cysts may disappear (53%), not change (28%), enlarge (11%), decrease (3%), or increase and decrease (6%). Adnexal cysts ≤5 cm in postmenopausal women are rarely malignant. TVS aspiration of adnexal cysts should be performed only when there is strong evidence of a benign etiology in order to avoid potential complications such as peritoneal contamination by ovarian cancer cells or pseudomyxoma peritonei. TVS aspiration plays an important role in the diagnosis and treatment of tubo-ovarian abscesses (TOAs). It may also be performed for symptomatic relief in cases of large peritoneal inclusion

cysts or benign ovarian cysts.

Solid or Complex Masses

Most solid adnexal masses are pedunculated leiomyomas (or "myomas" or "fibroids"). Leiomyomas are the most common uterine neoplasms and are prevalent in approximately 20% to 30% of women older than age 30. Pedunculated fibroids sometimes can be mistaken for solid ovarian masses. Careful search for and identification of normal ovaries that may be displaced by uterine myomas helps avoid this error.

Solid ovarian masses include benign ovarian tumors such as some cystic teratomas, fibromas, thecomas, malignant ovarian tumors (primary and metastatic), and a torsed ovary. The most common ovarian neoplasm in women of reproductive age is benign cystic teratoma, which has a broad spectrum of US appearances. When the diagnosis is in doubt, computed tomography (CT) or magnetic resonance imaging (MRI) can depict the fatty elements, teeth (7%), or bony fragments (18%) characteristic of these lesions. Most solid ovarian masses are removed surgically. Even benign solid masses, if large, present a risk of torsion. The risk of malignant degeneration in cystic teratomas is rare, reported as <1%.

Complex adnexal masses are usually ovarian in origin. In women of reproductive age these most commonly present as hemorrhagic cysts or endometriomas. The sonographic characteristics suggest the diagnosis, and a follow-up US can be done after two or three menstrual cycles to evaluate for resolution. The optimal time for this follow-up evaluation is within the first 7 to 10 days after the onset of the menses in order to avoid confusion with a new hemorrhagic cyst. Typically, hemorrhagic cysts will resolve, whereas endometriomas will persist. When atypical features are present, MRI can be useful to confirm the presence of endometriosis. In the appropriate clinical setting, TOAs, ectopic pregnancies, and adnexal torsion can present as complex masses. Therefore, a pregnancy test is important to narrow the differential diagnosis.

Even though US may distinguish malignant from benign neoplasms, it provides useful information. Various authors have devised morphologic scoring systems for pelvic masses to predict ovarian malignancy based on size, internal borders, and the presence of septa, papillary projections, and echogenicity. The presence of mural nodules or septations (especially with color Doppler flow) suggests that an adnexal mass is a neoplasm. Three-dimensional US morphologic assessment does not appear to improve the diagnosis of complex adnexal masses; however, the combination of three-dimensional US and three-dimensional color and duplex Doppler may contribute to the differentiation between benign and malignant masses because it improves detection of central blood vessels, which are more common in malignant lesions.

Color and Duplex Doppler

More recent studies have established that spectral Doppler US parameters (resistive index, pulsatility index, peak systolic velocity, time-averaged Vmax) do not provide any significant improvement over morphologic assessment; therefore, the value of spectral Doppler analysis is very limited. However, the use of color Doppler adds significant contributions to differentiating between benign and malignant masses and is recommended in all cases of complex masses. Malignant masses generally demonstrate neovascularity, with abnormal branching patterns or vessel morphology. Hence, color Doppler is indicated in the assessment of any complex or solid adnexal mass. Optimal sonographic evaluation is achieved by using a combination of gray-scale morphologic assessment and color or power Doppler imaging to detect flow within any solid areas. Three-dimensional (3D) power Doppler assessment of papillary projections or solid tumor areas may be helpful in reducing the false positive rate of benign complex cystic adnexal masses. Another recent study showed that 3D power Doppler increased the sensitivity rate from 88% to 99% with the Risk of Malignancy Index (based on menopausal status, serum CA-125, and US findings).

The combination of color Doppler with serum CA-125 has been proposed to increase sensitivity for differentiating benign from malignant ovarian tumors. When increasing the cutoff point of serum CA-125 from 35 U/mL to 65 U/mL in the presence of resistive index (RI) <0.5, the best specificity (100%) and positive predictive value (PPV) (100%) were reached. US imaging features such as hydronephrosis, ascites, pleural effusions, and liver, peritoneal, or omental metastases are important in evaluation of the extent of disease.

Magnetic Resonance Imaging

MRI can be used to determine the origin of a mass (uterine versus ovarian) and help distinguish benign from malignant masses with an overall accuracy for the diagnosis of malignancy of 91%. On MRI, identification of vegetations in cystic masses and ascites is the best indicator of malignancy. A meta-analysis comparing the incremental value of a second test to evaluate an indeterminate adnexal mass on gray-scale US found that contrast-enhanced MRI contributed to a greater change in the probability of ovarian cancer than CT, Doppler US, or MRI without contrast. In addition, MRI increases confidence in the diagnosis of mature cystic teratoma and leiomyoma. MRI is valuable for characterizing indeterminate adnexal masses seen on US, with a sensitivity for identifying malignancy of 100% and a specificity for benignity of 94%. In a prospective study of women with suspected adnexal masses, both US with Doppler and MRI were highly sensitive for characterizing lesions as malignant (US 100%, MRI 96.6%), but the specificity of MRI was significantly greater (US 39.5%, MRI 83.7%). Therefore, women who clinically have a low risk of malignancy but have complex lesions on US are the patients who will most likely benefit from contrast-enhanced MRI. More recent work states that the addition of diffusion- and perfusion-weighted MRI improved accuracy, compared to conventional MRI alone, with an accuracy rate of 95% with the combined technique.

Computed Tomography

CT is usually not indicated for the differential diagnosis of adnexal masses because of poor soft-tissue discrimination, except when identification of characteristic calcifications (such as teeth in a teratoma) or macroscopic fat is important to make the diagnosis. If the adnexal mass is thought to be malignant, CT may be indicated to stage a suspected primary ovarian cancer (see the NGC summary ACR Appropriateness Criteria® staging and follow-up of ovarian cancer) or to identify the primary intra-abdominal cancer (e.g., colon, gastric, pancreatic) with suspected ovarian metastases. Furthermore, CT involves ionizing radiation exposure, which has recently become much more of a concern in the scientific and lay literature for future cancer risks, and the principle of ALARA (as low as reasonably achievable) radiation dosing should be of paramount importance. With US and MRI well established, there is little reason presently to obtain a CT for adnexal pathology other than for cancer staging.

Positron Emission Tomography

The sensitivity and specificity of positron emission tomography (PET) in evaluating suspected adnexal masses in asymptomatic females are only 58% and 76%, respectively. However, PET may play a role in women with known history of malignancy who present for evaluation of an adnexal mass to identify other sites of disease. A small series of 18 patients showed that F18-FDG coincidence PET was of clinical value when assessing suspicious malignant adnexal masses. However, borderline (low malignant potential) tumors or leiomyomas can cause false-positive results with this technique.

Summary

- US remains the study of choice for evaluating a woman with a clinically suspected adnexal mass.
- Color or power Doppler US is an essential adjunct to gray-scale imaging. Spectral Doppler US has not been reliable or accurate in differentiating benign from malignant adnexal masses.
- US remains the most important modality for follow-up of adnexal masses.
- MRI is a valuable problem-solving tool when US is inconclusive or limited due to body habitus. Recent evidence supports the
 implementation of diffusion- or perfusion-weighted imaging in addition to conventional MR pulse sequences.
- To a lesser extent, CT is useful in selected cases when a nongynecologic origin of an adnexal mass is suspected. Despite its expediency, CT should not be used in most cases as the primary imaging tool, because of its nonspecificity and its use of ionizing radiation.

Anticipated Exceptions

Nephrogenic systemic fibrosis (NSF) is a disorder with a scleroderma-like presentation and a spectrum of manifestations that can range from limited clinical sequelae to fatality. It appears to be related to both underlying severe renal dysfunction and the administration of gadolinium-based contrast agents. It has occurred primarily in patients on dialysis, rarely in patients with very limited glomerular filtration rate (GFR) (i.e., <30 mL/min/1.73 m²), and almost never in other patients. There is growing literature regarding NSF. Although some controversy and lack of clarity remain, there is a consensus that it is advisable to avoid all gadolinium-based contrast agents in dialysis-dependent patients unless the possible benefits clearly outweigh the risk, and to limit the type and amount in patients with estimated GFR rates <30 mL/min/1.73 m². For more information, please see the American College of Radiology (ACR) Manual on Contrast Media (see the "Availability of Companion Documents" field).

Abbreviations

- CA-125, cancer antigen-125
- CT, computed tomography
- FDG-PET, fluorine-18-2-fluoro-2-deoxy-D-glucose positron emission tomography
- MRI, magnetic resonance imaging
- TAS, transabdominal sonography
- TVS, transvaginal sonography
- US, ultrasound

Relative Radiation Level Designations

Relative Radiation Level*	Adult Effective Dose Estimate Range	Pediatric Effective Dose Estimate Range
О	0 mSv	0 mSv
	<0.1 mSv	<0.03 mSv

Relative Radiation Level*	Adult Effective Dose Estimate Range	Pediatric Effective Dose Estimate Range
	1-10 mSv	0.3-3 mSv
	10-30 mSv	3-10 mSv
	30-100 mSv	10-30 mSv

^{*}RRL assignments for some of the examinations cannot be made, because the actual patient doses in these procedures vary as a function of a number of factors (e.g., region of the body exposed to ionizing radiation, the imaging guidance that is used). The RRLs for these examinations are designated as "Varies."

Clinical Algorithm(s)

Algorithms were not developed from criteria guidelines.

Scope

Disease/Condition(s)

Adnexal mass

Guideline Category

Diagnosis

Evaluation

Clinical Specialty

Family Practice

Internal Medicine

Obstetrics and Gynecology

Oncology

Radiology

Intended Users

Health Plans

Hospitals

Managed Care Organizations

Physicians

Utilization Management

Guideline Objective(s)

To evaluate the appropriateness of radiologic examinations for patients with clinically suspected adnexal mass

Target Population

Patients with clinically suspected adnexal mass

Interventions and Practices Considered

- 1. Ultrasound (US) pelvis
 - Transabdominal
 - Transvaginal
 - With Doppler
- 2. Magnetic resonance imaging (MRI) pelvis
 - Without and with contrast
 - Without contrast
- 3. Computed tomography (CT) pelvis
 - Without contrast
 - With contrast
 - Without and with contrast
- 4. Fluorine-18-2-fluoro-2-deoxy-D-glucose positron emission tomography (FDG-PET) whole body
- 5. Image-guided aspiration or biopsy adnexal mass

Major Outcomes Considered

- Utility of radiologic examinations in differential diagnosis
- Sensitivity and specificity of diagnostic imaging

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Literature Search Procedure

The Medline literature search is based on keywords provided by the topic author. The two general classes of keywords are those related to the condition (e.g., ankle pain, fever) and those that describe the diagnostic or therapeutic intervention of interest (e.g., mammography, MRI).

The search terms and parameters are manipulated to produce the most relevant, current evidence to address the American College of Radiology Appropriateness Criteria (ACR AC) topic being reviewed or developed. Combining the clinical conditions and diagnostic modalities or therapeutic procedures narrows the search to be relevant to the topic. Exploding the term "diagnostic imaging" captures relevant results for diagnostic topics.

The following criteria/limits are used in the searches:

- 1. Articles that have abstracts available and are concerned with humans.
- 2. Restrict the search to the year prior to the last topic update or in some cases the author of the topic may specify which year range to use in the search. For new topics, the year range is restricted to the last 5 years unless the topic author provides other instructions.
- 3. May restrict the search to Adults only or Pediatrics only.
- 4. Articles consisting of only summaries or case reports are often excluded from final results.

The search strategy may be revised to improve the output as needed.

Number of Source Documents

The total number of source documents identified as the result of the literature search is not known.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Strength of Evidence Key

- Category 1 The conclusions of the study are valid and strongly supported by study design, analysis, and results.
- Category 2 The conclusions of the study are likely valid, but study design does not permit certainty.
- Category 3 The conclusions of the study may be valid, but the evidence supporting the conclusions is inconclusive or equivocal.
- Category 4 The conclusions of the study may not be valid because the evidence may not be reliable given the study design or analysis.

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

The topic author drafts or revises the narrative text summarizing the evidence found in the literature. American College of Radiology (ACR) staff draft an evidence table based on the analysis of the selected literature. These tables rate the strength of the evidence for all articles included in the narrative text.

The expert panel reviews the narrative text, evidence table, and the supporting literature for each of the topic-variant combinations and assigns an appropriateness rating for each procedure listed in the table. Each individual panel member forms his/her own opinion based on his/her interpretation of the available evidence.

More information about the evidence table development process can be found in the ACR Appropriateness Criteria® Evidence Table Development document (see the "Availability of Companion Documents" field).

Methods Used to Formulate the Recommendations

Expert Consensus (Delphi)

Description of Methods Used to Formulate the Recommendations

Modified Delphi Technique

The appropriateness ratings for each of the procedures included in the Appropriateness Criteria topics are determined using a modified Delphi methodology. A series of surveys are conducted to elicit each panelist's expert interpretation of the evidence, based on the available data, regarding the appropriateness of an imaging or therapeutic procedure for a specific clinical scenario. American College of Radiology (ACR) staff distributes surveys to the panelists along with the evidence table and narrative. Each panelist interprets the available evidence and rates each

procedure. The surveys are completed by panelists without consulting other panelists. The ratings are a scale between 1 and 9, which is further divided into three categories: 1, 2, or 3 is defined as "usually not appropriate"; 4, 5, or 6 is defined as "may be appropriate"; and 7, 8, or 9 is defined as "usually appropriate." Each panel member assigns one rating for each procedure per survey round. The surveys are collected and the results are tabulated, de-identified and redistributed after each round. A maximum of three rounds are conducted. The modified Delphi technique enables each panelist to express individual interpretations of the evidence and his or her expert opinion without excessive bias from fellow panelists in a simple, standardized and economical process.

Consensus among the panel members must be achieved to determine the final rating for each procedure. Consensus is defined as eighty percent (80%) agreement within a rating category. The final rating is determined by the median of all the ratings once consensus has been reached. Up to three rating rounds are conducted to achieve consensus.

If consensus is not reached, the panel is convened by conference call. The strengths and weaknesses of each imaging procedure that has not reached consensus are discussed and a final rating is proposed. If the panelists on the call agree, the rating is accepted as the panel's consensus. The document is circulated to all the panelists to make the final determination. If consensus cannot be reached on the call or when the document is circulated, "No consensus" appears in the rating column and the reasons for this decision are added to the comment sections.

Rating Scheme for the Strength of the Recommendations

Not applicable

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

Internal Peer Review

Description of Method of Guideline Validation

Criteria developed by the Expert Panels are reviewed by the American College of Radiology (ACR) Committee on Appropriateness Criteria.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The recommendations are based on analysis of the current literature and expert panel consensus.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Selection of appropriate radiologic imaging procedures for the evaluation of patients with clinically suspected adnexal mass

Potential Harms

Transvaginal sonography (TVS) aspiration of adnexal cysts should be performed only when there is strong evidence of a benign etiology in order to avoid potential complications such as peritoneal contamination by ovarian cancer cells or pseudomyxoma peritonei.

Gadolinium-based Contrast Agents

Nephrogenic systemic fibrosis (NSF) is a disorder with a scleroderma-like presentation and a spectrum of manifestations that can range from limited clinical sequelae to fatality. It appears to be related to both underlying severe renal dysfunction and the administration of gadolinium-based contrast agents. It has occurred primarily in patients on dialysis, rarely in patients with very limited glomerular filtration rate (GFR) (i.e., <30 mL/min/1.73 m²), and almost never in other patients. Although some controversy and lack of clarity remain, there is a consensus that it is advisable to avoid all gadolinium-based contrast agents in dialysis-dependent patients unless the possible benefits clearly outweigh the risk, and to limit the type and amount in patients with estimated GFR rates <30 mL/min/1.73 m². For more information, see the American College of Radiology (ACR) Manual on Contrast Media (see the "Availability of Companion Documents" field).

Relative Radiation Level (RRL)

Potential adverse health effects associated with radiation exposure are an important factor to consider when selecting the appropriate imaging procedure. Because there is a wide range of radiation exposures associated with different diagnostic procedures, a relative radiation level indication has been included for each imaging examination. The RRLs are based on effective dose, which is a radiation dose quantity that is used to estimate population total radiation risk associated with an imaging procedure. Patients in the pediatric age group are at inherently higher risk from exposure, both because of organ sensitivity and longer life expectancy (relevant to the long latency that appears to accompany radiation exposure). For these reasons, the RRL dose estimate ranges for pediatric examinations are lower as compared to those specified for adults. Additional information regarding radiation dose assessment for imaging examinations can be found in the ACR Appropriateness Criteria® Radiation Dose Assessment Introduction document (see the "Availability of Companion Documents" field).

Qualifying Statements

Qualifying Statements

The American College of Radiology (ACR) Committee on Appropriateness Criteria and its expert panels have developed criteria for determining appropriate imaging examinations for diagnosis and treatment of specified medical condition(s). These criteria are intended to guide radiologists, radiation oncologists, and referring physicians in making decisions regarding radiologic imaging and treatment. Generally, the complexity and severity of a patient's clinical condition should dictate the selection of appropriate imaging procedures or treatments. Only those examinations generally used for evaluation of the patient's condition are ranked. Other imaging studies necessary to evaluate other co-existent diseases or other medical consequences of this condition are not considered in this document. The availability of equipment or personnel may influence the selection of appropriate imaging procedures or treatments. Imaging techniques classified as investigational by the U.S. Food and Drug Administration (FDA) have not been considered in developing these criteria; however, study of new equipment and applications should be encouraged. The ultimate decision regarding the appropriateness of any specific radiologic examination or treatment must be made by the referring physician and radiologist in light of all the circumstances presented in an individual examination.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

IOM Domain

Effectiveness

Identifying Information and Availability

Bibliographic Source(s)

Harris RD, Javitt MC, Glanc P, Brown DL, Dubinsky T, Harisinghani MG, Khati NJ, Kim YB, Mitchell DG, Pandharipande PV, Pannu HK, Podrasky AE, Royal HD, Shipp TD, Siegel CL, Simpson L, Wall DJ, Wong-You-Cheong JJ, Zelop CM, Expert Panel on Women's Imaging. ACR Appropriateness Criteria® clinically suspected adnexal mass. [online publication]. Reston (VA): American College of Radiology (ACR); 2012. 13 p. [44 references]

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

1996 (revised 2012)

Guideline Developer(s)

American College of Radiology - Medical Specialty Society

Source(s) of Funding

The American College of Radiology (ACR) provided the funding and the resources for these ACR Appropriateness Criteria®.

Guideline Committee

Committee on Appropriateness Criteria, Expert Panel on Women's Imaging

Composition of Group That Authored the Guideline

Panel Members: Robert D. Harris, MD, MPH (Principal Author); Marcia C. Javitt, MD (Panel Chair); Phyllis Glanc, MD (Panel Vice-chair); Douglas L. Brown, MD; Theodore Dubinsky, MD; Mukesh G. Harisinghani, MD; Nadia J. Khati, MD; Young Bae Kim, MD; Donald G. Mitchell, MD; Pari V. Pandharipande, MD, MPH; Harpreet K. Pannu, MD; Ann E. Podrasky, MD; Henry D. Royal, MD; Thomas D. Shipp, MD; Cary Lynn Siegel, MD; Lynn Simpson, MD; Darci J. Wall, MD; Jade J. Wong-You-Cheong, MD; Carolyn M. Zelop, MD

Financial Disclosures/Conflicts of Interest

Not stated

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Lev-Toaff AS, Horrow MM, Andreotti RF, Lee SI, DeJesus Allison SO, Bennett GL, Brown DL, Glanc P, Horowitz NS, Javitt MC, Podrasky AE, Scoutt LM, Zelop CM, Expert Panel on Women's Imaging. ACR Appropriateness Criteria® clinically suspected adnexal mass. [online publication]. Reston (VA): American College of Radiology (ACR); 2009. 9 p.

Guideline Availability
Electronic copies: Available from the American College of Radiology (ACR) Web site
Print copies: Available from the American College of Radiology, 1891 Preston White Drive, Reston, VA 20191. Telephone: (703) 648-8900.
Availability of Companion Documents
The following are available:
 ACR Appropriateness Criteria®. Overview. Reston (VA): American College of Radiology; 2 p. Electronic copies: Available in Portable Document Format (PDF) from the American College of Radiology (ACR) Web site ACR Appropriateness Criteria®. Literature search process. Reston (VA): American College of Radiology; 1 p. Electronic copies: Available in PDF from the ACR Web site ACR Appropriateness Criteria®. Evidence table development – diagnostic studies. Reston (VA): American College of Radiology; 2013 Nov. 3 p. Electronic copies: Available in PDF from the ACR Web site ACR Appropriateness Criteria®. Radiation dose assessment introduction. Reston (VA): American College of Radiology; 2 p. Electronic copies: Available in PDF from the ACR Web site ACR Appropriateness Criteria®. Manual on contrast media. Reston (VA): American College of Radiology; 90 p. Electronic copies: Available in PDF from the ACR Web site ACR Appropriateness Criteria®. Procedure information. Reston (VA): American College of Radiology; 1 p. Electronic copies: Available in PDF from the ACR Web site ACR Appropriateness Criteria® clinically suspected adnexal mass. Evidence table. Reston (VA): American College of Radiology; 2012. 16 p. Electronic copies: Available from the ACR Web site
Patient Resources
None available
NGC Status
This NGC summary was completed by ECRI on February 13, 2006. This NGC summary was updated by ECRI Institute on June 15, 2010 and on January 13, 2011 following the U.S. Food and Drug Administration (FDA) advisory on gadolinium-based contrast agents. This summary was updated by ECRI Institute on May 9, 2013.
Copyright Statement
Instructions for downloading, use, and reproduction of the American College of Radiology (ACR) Appropriateness Criteria® may be found on the ACR Web site

Disclaimer

NGC Disclaimer

The National Guideline Clearinghouseâ, & (NGC) does not develop, produce, approve, or endorse the guidelines represented on this site.

All guidelines summarized by NGC and hosted on our site are produced under the auspices of medical specialty societies, relevant professional associations, public or private organizations, other government agencies, health care organizations or plans, and similar entities.

Guidelines represented on the NGC Web site are submitted by guideline developers, and are screened solely to determine that they meet the NGC Inclusion Criteria which may be found at http://www.guideline.gov/about/inclusion-criteria.aspx.

NGC, AHRQ, and its contractor ECRI Institute make no warranties concerning the content or clinical efficacy or effectiveness of the clinical practice guidelines and related materials represented on this site. Moreover, the views and opinions of developers or authors of guidelines represented on this site do not necessarily state or reflect those of NGC, AHRQ, or its contractor ECRI Institute, and inclusion or hosting of guidelines in NGC may not be used for advertising or commercial endorsement purposes.

Readers with questions regarding guideline content are directed to contact the guideline developer.